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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/736,545	12/17/2003	Masahiro Kawaguchi	03500.017338	6817
5514	7590	09/22/2006	EXAMINER	
FITZPATRICK CELLA HARPER & SCINTO 30 ROCKEFELLER PLAZA NEW YORK, NY 10112			LIU, SUE XU	
			ART UNIT	PAPER NUMBER
			1639	
DATE MAILED: 09/22/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/736,545

Applicant(s)

KAWAGUCHI ET AL.

Examiner

Sue Liu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 6-27 is/are pending in the application.
- 4a) Of the above claim(s) 1 and 8-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,6 and 7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 27 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6/26/06.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Status

Claims 3-5 have been canceled as filed on 6/26/06;

Claim 27 has been added as filed on 6/26/06;

Claims 1, 2, and 6-27 are currently pending;

Claims 1 and 8-27 have been withdrawn;

Claims 2, 6 and 7 are being examined in this application.

Election/Restrictions

1. Applicant's election of Group II (Claims 2-7) in the reply entered on 11/14/2005 was previously acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election **without traverse** (MPEP § 818.03(a)).
2. Applicant's non-election of Claims 1 and 8-26 in the reply entered on 11/14/2005 was previously acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election **without traverse** (MPEP § 818.03(a)).
3. Claims 1 and 8-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without traverse** in the reply entered on 11/14/2005 as previously acknowledged.

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4. Newly submitted Claim 27 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Inventions of Group II (Claims 2, 6 and 7) and Claim 27 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product of Group II (Claims 2, 6, and 7) can be used in different processes from the method (nucleic acid detection) recited in Claim 27. For examples, the DNA array of Group II (Claims 2, 6, and 7) can be used to screen for DNA binding proteins; it can be used as barcode for biological sample tracking; it can also be used for aptamer sandwich assays.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 27 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined

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claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

6. Applicants also elected the following species as previously acknowledged:

- A.) fluorescent markers;
- B.) two kinds of external standard probes;
- C.) one kind of internal standard probes;
- D.) single-stranded DNA;
- E.) 20 residues each of internal and external probes;
- F.) two sets of primers that will produce 500 bp and 200 bp products;
- G.) a "microorganism" is selected as the most specific species explicitly recited in the specification;
- H.) one nucleic acid;
- I.) two.

Priority

7. This application appears to be a CONTINUATION of PCT/JP03/07918 filed on 6/23/03.

Receipt is acknowledged of the following papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file:

A.) An application filed in JAPAN (2002-191390) on 6/28/2002.

B.) An application filed in JAPAN (2002-183249) on 6/24/2002.

Claim Rejections Withdrawn

19. Upon further consideration, and in light of applicants' amendments to the claims and supporting arguments, the following claim rejections as set forth in the previous Office action are withdrawn:

A.) Claims 2-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

B.) Claims 2-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim Rejections Maintained

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

20. Claims 2, 6 and 7 as amended or originally filed are rejected under 35 U.S.C. 102(b) as being anticipated by Dudley et al (PNAS. Vol. 99: 7554-7559. May 28, 2002). The previous rejection is maintained for the reasons of record as set forth in the Office action, mailed 12/21/05, at p. 9-11.

Discussion and Answer to Argument

21. Applicant's arguments have been fully considered but they are not persuasive for the following reasons (in addition to reasons of record). Each point of applicant's traversal is addressed below (applicant's arguments are in italic):

Applicants argue that the cited reference (Dudley et al) does not teach all the features as indicated in the followings:

"According to a feature of the invention as recited by Claim 2, the assay contains at least two probes for external standard nucleic acids, where the at least two probes have sequences different from each another and complementary to the external nucleic acids, and where the at least two probes are available for producing calibration curves for detecting an amount of the nucleic acid molecules having the target base sequences in the sample."

(Reply entered 6/26/06, at p. 12, para 4)

Contrary to applicant's assertion, the Dudley reference does teach at least two probes for external standard nucleic acids as discussed in the previous Office action, and the previous rejection is herein incorporated by reference in its entirety.

Dudley et al teach measuring absolute expression with microarrays with calibrated reference samples (See Abstract of the reference). The reference teaches microarrays comprising probes generated from yeast ORF PCR product set, and a set of differentially labeled oligonucleotides of known abundance containing sequences complementary to every spot on the array (See p. 7554, right column, para 2 of the reference). The set of oligonucleotides reads on at least two different "external" probes for the external standards because the oligonucleotides sequences are known and different from each other (or from the target sequences). In addition, any probe for any one of the >6,000 genes that is not considered as the gene of interest (the target gene) and is not complementary to the target gene sequence reads on an "external probe". For examples, probes for the RPL29, or the PHO88 genes listed in Figure 3 at p. 7557 of the reference read on the at least two different external probes.

The recitation "where the at least two probes are available for producing calibration curves for detecting an amount of the nucleic acid molecules having the target base sequences in the sample" is construed as an intended use of the claimed product. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Because no structural difference has been demonstrated between the Dudley reference's teaching and the

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instant claimed microarray, the microarray taught by the Dudley reference is capable of performing the instant claimed intended use.

Furthermore, the Dudley reference teaches using calibration curves to analyze the microarray hybridization results (see Figures 1 and 2, for examples), where the amount of DNA is derived based on the hybridization intensities of different spots based on linear regression (calibration curves) analysis. Thus, the Dudley reference teaches the recited intended use of the instant claims.

Applicants also argue that Claims 6, 7 and 27 are to be patentable and separate and individual considerations are requested.

First, Claim 27 is withdrawn from consideration as drawn to an invention non-elected by original presentation, as discussed above in the "Election/Restriction" of the instant Office action.

The teaching of the Dudley reference anticipates Claims 6 and 7 as discussed in detail in the previous Office action mailed 12/21/05, at p. 9-11.

The Dudley reference teaches that the microarray are generated either by printing PCR generated cDNA or commercially available oligo sets (See Supplemental Web Site as described on p. 7555, left column, last paragraph of the reference), which reads on the synthetic nucleic acids immobilized on the substrate as recited in the instant Claim 6. The reference teaches the oligo reference sample is 20 bases long (p. 7554, right column, para 4 of the reference), which reads on the nucleic acid has a chain length of 15 to 75 bases as recited in the instant Claim 7.

22. Claims 2, 6 and 7 are rejected under 35 U.S.C. **102(b)** as being anticipated by Delenstarr et al (US PGPUB 2002/0051973 A1; May 2, 2002). The previous rejection is maintained for the reasons of record as set forth in the Office action, mailed 12/21/05, at p. 11.

Discussion and Answer to Argument

23. Applicant's arguments have been fully considered but they are not persuasive for the following reasons (in addition to reasons of record). Each point of applicant's traversal is addressed below (applicant's arguments are in italic):

Applicants traversed the rejection over the Delenstarr reference with the same arguments as the traversal over the Dudley reference.

Contrary to applicant's assertion, the Delenstarr reference does teach at least two probes for external standard nucleic acids as discussed in the previous Office action, and the previous rejection is herein incorporated by reference in its entirety.

The Delenstarr reference teaches arrays comprising background probes (Claims 1-4 of the reference) that do not selectively hybridize to target nucleotide sequence (Claims 2 and 4 of the reference), which reads on the at least two different external probes. In addition, the reference teaches the array comprising target probes, test-background probes, and standard-background probes (See Claim 30 of the reference), which also read on the at least two different external probes.

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Similar to the discussion above, the limitation “where the at least two probes are available for producing calibration curves for detecting an amount of the nucleic acid molecules having the target base sequences in the sample” is construed as an intended use of the instant claimed product. As discussed above, the intended use recitation does not provide a structural difference between the instant claimed product and the reference’s teaching.

In addition, the Delenstarr reference teaches using the background probe (reads on external probes) signals to determine (or calibrate) the target sequence hybridization (see Example 7, and Figures). In Example 7, the reference discusses in detail data analysis using various algorithms and curve analysis, which reads on the intended use limitation as recited in the instant Claim 2.

Applicants also argue that Claims 6, 7 and 27 are to be patentable and separate and individual considerations are requested.

First, Claim 27 is withdrawn from consideration as drawn to an invention non-elected by original presentation, as discussed above in the “Election/Restriction” of the instant Office action.

The teaching of the Delenstarr reference anticipates Claims 6 and 7 as discussed in detail in the previous Office action mailed 12/21/05, at p. 11.

The reference teaches the probes are 25 bases long (such as SEQ ID NO 5 as recited in Claim 5, for example), which reads on the limitation of the instant Claim 7. The reference further teaches that the probes can be synthesized (See paragraph [0104] of the reference), which reads on the synthetic probes of the instant Claim 6.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sue Liu whose telephone number is 571-272-5539. The examiner can normally be reached on M-F 9am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SL
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9/5/2006

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